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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/071,395

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Michael L. Bell

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EXAMINER

YU, MELANIE J

ART UNIT

PAPER NUMBER

1641

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/071,395	Applicant(s) BELL, MICHAEL L.	
	Examiner MELANIE YU	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____. | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) <input type="checkbox"/> Notice of Informal Patent Application
6) <input type="checkbox"/> Other: _____. |
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DETAILED ACTION

Applicant's amendment filed 24 March 2008 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 25-29 and 31- 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagasawa et al. (US 6,897,021) in view of Cronin et al. (US 6,045,996).

Nagasawa et al. teach a method of providing a plurality of supports, wherein for each of the multiple target analytes to be assayed, a solid support is provided which comprises a bound binding ligand capable of specifically binding to the target analyte (col. 2, lines 47-55; col. 8, lines 3-9; col. 8, lines 52-57; col. 13, lines 7-14); using the supports for detection of analyte in a sample, wherein the sample is incubated in the presence of the supports (sample is labeled and allowed to flow over the chip to bind to

the receptive material, col. 1, lines 31-37; reactive probe chips are used for detection of analyte in a sample, col. 13, lines 7-14, and would therefore use the detection method described in the "background of the invention" section); and the presence of each of the target analyte to be assayed is determined by determining the extent of binding between the target analyte and the solid support bound binding ligand (detection of fluorescence is detected and quantified, col. 1, lines 34-36). Nagasawa et al. do not specifically teach the support providing a steric interference that hinders the ability to bind the binding ligand, but does not hinder the binding of other target analytes to other binding ligands. However, the specific at page 17 describes that beads preferably have a pore diameter of 50 nm and made of controlled pore glass to provide this limitation. Nagasawa et al. teach that the pores size may be 50 nm (example 3, col. 10) and the porous material is controlled pore glass (example 3, col. 10), and therefore provide, or is capable of providing, the steric interference as recited by instant claims 25 and 26. Nagasawa et al. fail to teach incubation of the sample in the presence of the supports in a single reaction vessel.

Cronin et al. teach a biochip with a plurality of DNA binding regions (col. 3, lines 30-37) placed within a reaction vessel (contact between array and sample takes place in a container, col. 5, lines 35-38) and incubation under conditions that permit binding between multiple binding ligands on the biochip and a sample in a single reaction vessel (incubation takes place under conditions for hybridization to take place in a single container, col. 5, lines 34-51), in order to provide detection of analyte in a sample (col. 5, lines 52-58).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Nagasawa et al., placement of a plurality of supports in a plurality of reaction vessels for incubation with different samples as taught by Cronin et al., in order to provide easy introduction and removal of samples and other fluids and accurately control the incubation temperature required for hybridization.

With respect to claims 27 and 31, the pore sizes of Nagasawa et al. are the same as the pore sizes taught in the instant specification for steric interference and therefore the pores of Nagasawa et al. are capable of providing the same steric interference as that recited in the instant claims.

Regarding claims 28, 29, 33 and 34, Nagasawa et al. teach detection in the presence of a detectably labeled ligand-binding molecule and determining the presence of the label, wherein the label is a fluorescent label (col. 1, lines 31-39) and incubating the solid support in the presence of the detectably labeled binding ligand (fluorescently labeled DNA, col. 1, lines 31-37).

2. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shipwash et al. (US 2005/0164264, provisional application filed August 2000) in view of Nagasawa et al. (US 6,897,021).

Shipwash et al. teach a method comprising: providing a plurality of solid supports (different biomolecules bound to different types of microspheres, par. 185), wherein a solid support comprises a bound binding ligand capable of specific binding to each of a multiple target analytes to be assayed (multiple labels are used to detect multiple

analyte, par. 44 and 185) and the solid support may be a porous bead (par. 264); incubating a sample in the presence of the supports under conditions sufficient to permit binding between multiple sets of binding ligands (binding assays are performed in the reaction vesicle, therefore an incubation occurs under conditions that provide binding for all analyte of interest, par. 185) and corresponding target analytes in a single reaction vessel (plurality of binding assays performed in the same reaction vesicle, par. 185); and determining for each of the multiple target analytes to be assayed the presence or absence of the target analyte by determining the extent of binding between the target analyte and the solid support bound binding ligand (par. 185). Fulton fails to teach the ability of the target analyte to bind to the binding ligand of the support hindered by steric interference that does not hinder the binding of other target analytes.

Nagasawa et al. teach binding ligands bound within porous particle structures (col. 6, lines 25-33; col. 2, lines 46-55) and a pore size of 50 nm (example 3, col. 10), in order to provide a pore size that allows diffusion of the detection target through the porous material. Nagasawa et al. do not specifically teach the support providing a steric interference that hinders the ability to bind the binding ligand, but does not hinder the binding of other target analytes to other binding ligands. However, the specific at page 17 describes that beads preferably have a pore diameter of 50 nm and made of controlled pore glass to provide this limitation. Nagasawa et al. teach that the pores size may be 50 nm (example 3, col. 10) and the porous material is controlled pore glass (example 3, col. 10), and therefore provide, or is capable of providing, the steric interference as recited by instant claims 25 and 26.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Shipwash et al., ligands immobilized within the pores and a specific pore size of 50 nm as taught by Nagasawa et al., in order to prevent side-reaction with contaminants and a larger reactive surface area which allows for more accurate detection.

Regarding claims 30 and 35, Shipwash et al. teach detection of the microspheres using flow cytometry (par. 187 and 278-279).

Response to Arguments

3. The rejections under 35 USC 112, second paragraph have been withdrawn in response to applicant's arguments. Applicant's arguments filed 24 March 2008 regarding the rejections under 35 USC 103(a) have been fully considered but they are not persuasive. Applicant argues that the prior art fails to teach a method that requires at least one target analyte wherein its binding is hindered by a steric interference, whereas for at least one other target analyte its binding to its corresponding ligand is not hindered. Applicant further argues that the pending claims are method claims and therefore the prior must explicitly teach the use of steric interference. Applicant argues that Nagasawa does not teach the feature of steric interference and an inherent property alone is insufficient to provide a limitation recited in method claims because the reference must teach a step actively using the steric interference in a differential manner. Applicant's amendment is not persuasive because the limitation of having the "ability" of hindering the binding ligand to a support by steric interference and not hindering the binding of other target analyte to other binding ligand for at least one other

target analyte is drawn to an intended use of the structure, and is not a method step required for the method. Since this limitation is an intended use, the prior art does not have to specifically teach the intended use, but the solid support of the prior art must be capable of performing the recited intended use. As described above, Nagasawa et al. teach the same pore size as the instant specification, wherein the pore size is used to provide the steric hindrance, and therefore is capable of performing the recited differential steric hindrance.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MELANIE YU** whose telephone number is (571)272-2933. The examiner can normally be reached on **M-F 8:30-5**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Yu/
Patent Examiner, Art Unit 1641

/Long V Le/
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